



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
2003-DT-06

Food and Drug Administration
Detroit District
300 River Place
Suite 5900
Detroit, MI 48207
Telephone: 313-393-8100
FAX: 313-393-8139

December 17, 2002

Mr. Paul Ramer, Owner
Paul Ramer Construction
8287 East 12B Road
Argos, Indiana 46501

Dear Mr. Ramer:

During an investigation of your dairy farm located at 8287 East 12B Road, Argos, Indiana 46501, on March 21-22, 2002 a Food and Drug Administration (FDA) investigator found that you caused the adulteration of a new animal drug within the meaning of Section 501(a)(5) of the Federal Food, Drug, and Cosmetic Act (The Act) and of a medicated animal feed within the meaning of section 501(a)(6) of the Act. From approximately June 17, 1999 through March 12, 2002, you continuously fed [REDACTED] medicated feed containing the new animal drug [REDACTED] to your lactating dairy cows. [REDACTED] has not been approved for use in lactating dairy cows as provided in 21 CFR 558.95. By feeding the [REDACTED] medicated feed to your lactating dairy cows, you used [REDACTED] in a manner that does not conform with an approved new animal drug application as required by section 512(a)(1) of the Act. For this reason, the drug is unsafe under section 512 of the Act and thus adulterated under section 501(a)(5) of the Act. The medicated feed you fed to your lactating dairy cows is unsafe under section 512(a)(2) of the Act because it bears or contains a new animal drug that does not conform with an approved application. The feed is thus adulterated under section 501(a)(6) of the Act.

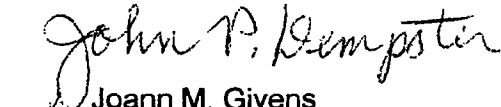
During the inspection, you told the FDA investigator that the milk from cows that were fed the [REDACTED] medicated feed was sold to [REDACTED] for human food. You should ensure that you have an adequate system for assuring that your dairy cows are treated only with drugs that are approved for use in lactating dairy cows. In addition, you should assure that animals and animal-derived food products, such as milk, have been withheld from slaughter and/or shipment for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues.

The above is not intended as an all-inclusive list of violations. As a producer of animals and animal products offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law. You should take prompt action to correct these violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

You should notify this office, in writing, within fifteen (15) working days of the receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 30 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Mr. David M. Kaszubski, Director Compliance Branch, at the above address.

Sincerely yours,


Joann M. Givens
for District Director
Detroit District Office